MANNKIND CORP
Form 10-Q
May 10, 2011

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2011

Or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from __________ to __________.

Commission file number: 000-50865

MannKind Corporation
(Exact name of registrant as specified in its charter)

Delaware	**13-3607736**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
28903 North Avenue Paine Valencia, California	**91355**
(Address of principal executive offices)	*(Zip Code)*

(661) 775-5300
(*Registrant s telephone number, including area code)*

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

As of April 22, 2011, there were 130,685,116 shares of the registrant s common stock, $.01 par value per share, outstanding.

MANNKIND CORPORATION
Form 10-Q
For the Quarterly Period Ended March 31, 2011
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AFREZZA®, MedTone® and Technosphere® are our registered trademarks in the United States. We have also applied for and have registered company trademarks in other jurisdictions, including Europe and Japan.

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PART 1: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands except share data)

	March 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,912	$ 66,061
Marketable securities	549	4,370
State research and development credit exchange receivable current	674	674
Prepaid expenses and other current assets	2,479	2,849
Total current assets	50,614	73,954
Property and equipment net	203,179	202,356
State research and development credit exchange receivable net of current portion	729	629
Other assets	230	317
Total	$ 254,752	$ 277,256
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 5,360	$ 3,294
Accrued expenses and other current liabilities	19,035	14,840
Total current liabilities	24,395	18,134
Senior convertible notes	209,655	209,335
Note payable to related party	224,203	235,319
Total liabilities	458,253	462,788
Commitments and contingencies		
Stockholders deficit:		
Undesignated preferred stock, $0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at March 31, 2011 and December 31, 2010		
Common stock, $0.01 par value 200,000,000 shares authorized; 130,674,783 and 127,793,178 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	1,307	1,278
Additional paid-in capital	1,611,373	1,587,858
Accumulated other comprehensive income	86	74
Deficit accumulated during the development stage	(1,816,267)	(1,774,742)
Total stockholders deficit	(203,501)	(185,532)

Total	$	254,752	$	277,256

See notes to condensed consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three months ended March 31, 2011	Three months ended March 31, 2010	Cumulative period from February 14, 1991 (date of inception) to March 31, 2011
Revenue	$ 50	$	$ 3,131
Operating expenses:			
Research and development	26,289	30,491	1,292,381
General and administrative	11,762	10,110	351,363
In-process research and development costs			19,726
Goodwill impairment			151,428
Total operating expenses	38,051	40,601	1,814,898
Loss from operations	(38,001)	(40,601)	(1,811,767)
Other income (expense)	1,350	(790)	(1,267)
Interest expense on note payable to related party	(2,476)	(2,102)	(19,927)
Interest expense on senior convertible notes	(2,413)	(1,210)	(20,266)
Interest income	15	3	36,986
Loss before provision for income taxes	(41,525)	(44,700)	(1,816,241)
Income taxes			(26)
Net loss	(41,525)	(44,700)	(1,816,267)
Deemed dividend related to beneficial conversion feature of convertible preferred stock			(22,260)
Accretion on redeemable preferred stock			(952)
Net loss applicable to common stockholders	$ (41,525)	$ (44,700)	$ (1,839,479)
Net loss per share applicable to common stockholders basic and diluted	$ (0.34)	$ (0.40)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	121,057	113,095	

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Three months ended March 31, 2011	2010	Cumulative Period from February 14, 1991 (Date of Inception) to March 31, 2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (41,525)	$ (44,700)	$ (1,816,267)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,119	4,314	100,582
Stock-based compensation expense	2,708	3,749	116,130
Stock expense for shares issued pursuant to research agreement			3,018
Loss on sale, abandonment/disposal or impairment of property and equipment			23,575
Accrued interest on investments, net of amortization of discounts			(191)
In-process research and development			19,726
Goodwill impairment			151,428
Loss on available-for-sale securities			873
Other, net	5	(3)	1,109
Changes in assets and liabilities:			
State research and development credit exchange receivable	(100)	1,265	(1,403)
Prepaid expenses and other current assets	370	455	(879)
Other assets	87		(230)
Accounts payable	(218)	1,208	1,484
Accrued expenses and other current liabilities	3,850	(4,786)	17,779
Other liabilities			(2)
Net cash used in operating activities	(30,704)	(38,498)	(1,383,268)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities			(796,779)
Sales/ maturities of marketable securities	3,828		796,393
Purchase of property and equipment	(1,993)	(1,689)	(322,244)
Proceeds from sale of property and equipment			284
Net cash provided by (used in) investing activities	1,835	(1,689)	(322,346)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants, net	9,746	473	1,228,826
Collection of Series C convertible preferred stock subscriptions receivable			50,000

Issuance of Series B convertible preferred stock for cash			15,000
Cash received for common stock to be issued			3,900
Repurchase of common stock			(1,028)
Put shares sold to majority stockholder			623
Borrowings under lines of credit			4,220
Proceeds from notes receivables			1,742
Borrowings on notes payable to related party		40,000	322,000
Principal payments on notes payable to principal stockholder			(70,000)
Borrowings on notes payable			3,460
Principal payments on notes payable			(1,667)
Proceeds from senior convertible notes			207,050
Payment of employment taxes related to vested restricted stock units	(26)	(1,253)	(11,600)
Net cash provided by financing activities	9,720	39,220	1,752,526
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	$ (19,149)	$ (967)	$ 46,912
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	66,061	30,019	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 46,912	$ 29,052	$ 46,912
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$	$	$ 26
Interest paid in cash	5,504	1,873	37,653
Accretion on redeemable convertible preferred stock			(952)
Issuance of common stock upon conversion of notes payable			3,331
Increase in additional paid-in capital resulting from merger			171,154
Issuance of common stock for notes receivable			2,758
Issuance of put option by stockholder			(2,949)
Put option redemption by stockholder			1,921
Issuance of Series C convertible preferred stock subscriptions			50,000
Issuance of Series A redeemable convertible preferred stock			4,296
Conversion of Series A redeemable convertible preferred stock			(5,248)
Non-cash construction in progress and property and equipment	4,371	1,025	4,371
Cancellation of principal on note payable to related party	11,116		27,797

In connection with the Company s initial public offering, all shares of Series B and Series C convertible preferred stock, in the amount of $15.0 million and $50.0 million, respectively, automatically converted into common stock in August 2004.

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of business and basis of presentation

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries (the Company), have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These statements should be read in conjunction with the financial statements and notes thereto included in the Company s latest audited annual financial statements. The audited statements for the year ended December 31, 2010 are included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2010 filed with the SEC on March 16, 2011 (the Annual Report).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three months ended March 31, 2011 may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these accompanying financial statements involve assessing long-lived assets for impairment, accrued expenses, the valuation of stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets.

Business The Company is a biopharmaceutical company focused on the discovery and development of therapeutic products for diseases such as diabetes and cancer. The Company s lead product candidate, AFREZZA (insulin human [rDNA origin]) Inhalation Powder, is an ultra rapid-acting insulin therapy in late-stage clinical investigation for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia.

AFREZZA consists of the Company s proprietary Technosphere particles onto which insulin molecules are loaded. These loaded particles are then aerosolized and inhaled deep into the lung using the Company s AFREZZA inhaler.

Basis of Presentation The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. Since its inception through March 31, 2011 the Company has reported accumulated net losses of $1.8 billion, which include a goodwill impairment charge of $151.4 million, and cumulative negative cash flow from operations of $1.4 billion. It is costly to develop therapeutic products and conduct clinical trials for these products. At March 31, 2011 the Company s capital resources consisted of cash, cash equivalents, and marketable securities of $47.5 million and $98.0 million of available borrowings under the loan agreement with an entity controlled by the Company s principal stockholder (see Note 12 Related-party arrangements). Based upon the Company s current expectations, management believes the Company s existing capital resources will enable it to continue planned operations through the first quarter of 2012. However, the Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. If the Company is not successful in raising additional capital through equity or debt financing, entering a business collaboration, establishing other funding facilities, licensing arrangements, assets sales or other means, or increasing the borrowings available under the loan arrangement with its related party, the Company will be required to reduce expenses through the delay, reduction or curtailment of its projects, including AFREZZA development activities, or further reduction of costs for facilities and administration, and there will be substantial doubt about its ability to continue as a going concern.

Fair Value of Financial Instruments The carrying amounts of financial instruments, which include cash equivalents, marketable securities and accounts payable, approximate their fair values due to their relatively short maturities. The fair value of the note payable to related party cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment.

Cash equivalents consist of highly liquid investments, with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash. As of March 31, 2011 and December 31, 2010, the Company held $35.0 million and $52.8 million, respectively of cash equivalents, consisting of money market funds, U.S. Treasury notes and commercial paper. The fair

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value of these investments was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

The Company s marketable securities consist principally of a certificate of deposit with a maturity greater than 90 days, held as collateral for the Company s commercial card programs and a common stock investment that are classified as available-for-sale securities. The certificate of deposit is stated at fair value based on quoted prices for similar instruments in an active market (Level 2 in the fair value hierarchy) and the common stock investment is stated at fair value based on quoted prices in an active market (Level 1 in the fair value hierarchy). As of March 31, 2011 and December 31, 2010, there were marketable securities of $0.5 million and $4.4 million, respectively.

The following is a summary of the carrying values and estimated fair values of the Company s senior convertible notes due in 2013 and 2015 (in millions).

	March 31, 2011		December 31, 2010	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
Notes due 2013	$ 113.4	$ 55.8	$ 113.3	$ 69.1
Notes due 2015	$ 96.2	$ 75.4	$ 96.0	$ 134.1

The senior convertible notes due 2013 estimated fair value was calculated based on quoted prices in an active market (Level 1 in the fair value hierarchy). The senior convertible notes due 2015 estimated fair value was calculated based on model-derived valuations whose inputs are observable (Level 2 in the fair value hierarchy).

Derivative financial instruments are reported in Other assets or Accrued expenses and other current liabilities in the condensed consolidated balance sheets and measured at fair value. The fair value of foreign exchange hedging contracts equals the carrying value at each balance sheet date. The fair value of these contracts are determined using methodologies based on market observable inputs (Level 2 in the fair value hierarchy), including foreign currency spot rates. The Company has used derivative financial instruments to manage its exposure to foreign currency exchange risks related to quarterly purchases on insulin. The Company does not use derivative financial instruments for trading or speculative purposes, nor does it use leveraged financial instruments. Credit risk related to derivative financial instruments is considered minimal and is managed by requiring high credit standards for counterparties and through periodic settlements of positions.

The Company s derivative financial instruments are not designated as hedging instruments, and gains or losses resulting from changes in the fair value are reported in Other income (expense) , in the condensed consolidated statements of operations. The Company entered into foreign exchange hedging contracts with notional amounts totaling zero and $25.5 million at March 31, 2011 and December 31, 2010, respectively. The Company recorded an unrealized loss of $567,000 on the outstanding contracts at December 31, 2010. The Company recorded a realized gain of $1.3 million and a realized loss of $288,000 related to these foreign exchange hedging contracts for the quarters ended March 31, 2011 and 2010, respectively. The Company terminated these contracts during the quarter ended March 31, 2011.

2. Investment in securities

The following is a summary of the available-for-sale securities classified as current assets (in thousands).

	March 31, 2011			December 31, 2010		
	Cost Basis	Gross Unrealized Gain	Fair Value	Cost Basis	Gross Unrealized Gain	Fair Value
Available-for-sale securities	$ 467	$ 82	$ 549	$ 4,295	$ 75	$ 4,370

The Company s available-for-sale securities at March 31, 2011 consist of a $0.4 million certificate of deposit with a maturity greater than 90 days, held as collateral for the Company s commercial card programs, and a common stock investment. The Company s available-for-sale securities at December 31, 2010 consist principally of $4.2 million of certificates of deposit with a maturity greater than 90 days, held as collateral primarily for foreign exchange hedging instruments, and a common stock investment. Gross realized gains and losses for available-for-sale securities were insignificant and recorded as Other income (expense) in the condensed consolidated statements of operations. Gross unrealized gains and losses are included in Other comprehensive gain (loss) (see Note 5 Comprehensive loss).

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3. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities are comprised of the following (in thousands):

	March 31, 2011	December 31, 2010
Salary and related expenses	$ 11,040	$ 5,624
Research and clinical trial costs	780	668
Accrued interest	4,481	4,993
Construction in progress	73	149
Other	2,661	3,406
Accrued expenses and other current liabilities	$ 19,035	$ 14,840

4. Accounting for stock-based compensation

Total stock-based compensation expense was $2.7 million and $3.7 million for the three months ended March 31, 2011 and 2010, respectively. The Company issued stock awards to employees during the quarter ended March 31, 2011 with two year vesting. The grant date fair value of the 1,467,500 stock options and 1,181,100 restricted stock units issued during the quarter ended March 31, 2011 were $3.7 million and $4.5 million, respectively, with a grant date fair value per share of $3.80.

As of March 31, 2011, there was $16.2 million and $21.4 million of unrecognized compensation cost related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 2.5 years.

5. Comprehensive loss

Accounting Standards Codification (ASC) 220-10-45 *Comprehensive Income Other Presentation* requires reporting and displaying comprehensive income (loss) and its components, which, for the Company, includes net loss and unrealized gains and losses on investments and cumulative translation gains and losses. In accordance with this guidance, the accumulated balance of other comprehensive income (loss) is disclosed as a separate component of stockholders equity. For the three months ended March 31, 2011 and 2010, comprehensive loss consisted of (in thousands):

	Three months ended March 31, 2011	Three months ended March 31, 2010
Net loss	$ (41,525)	$ (44,700)
Other comprehensive gain (loss):		
Unrealized gain on investments	7	13
Cumulative translation gain (loss)	5	(3)
Comprehensive loss	$ (41,513)	$ (44,690)

6. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing loss applicable to common stockholders by the weighted average number of common shares outstanding during the period excluding the shares loaned under the share lending arrangement (see Note 10 Common and preferred stock). As of March 31, 2011, 9,000,000 shares of the Company s common stock, which were loaned to a share borrower pursuant to the terms of a share lending agreement as described in Note 10, were issued and are outstanding, and holders of the borrowed shares have all the rights of a holder of the Company s common stock. However, because the share borrower must return all borrowed shares to the Company (or, in certain circumstances, the cash value thereof), the borrowed shares are not considered outstanding for the purpose of computing and reporting basic or diluted earnings (loss) per share. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes, that are not included in the diluted net loss per share calculation consisted of an aggregate of 33,334,623 shares and 17,209,289 shares as of March 31, 2011 and 2010, respectively, and exclude the 9,000,000 shares loaned under the share lending arrangement.

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7. Restructuring charges

On February 10, 2011, the Company announced that following receipt of the Complete Response letter from the United States Food and Drug Administration (FDA) regarding the new drug application (NDA) for AFREZZA, it implemented a restructuring to streamline operations, reduce operating expenses, extend the cash runway and focus its resources on securing the FDA s approval of the NDA for AFREZZA. In connection with the restructuring, the Company reduced its total workforce by approximately 41% to 257 employees. The Company recorded charges of approximately $6.7 million for employee severance and other related termination benefits and recognized a liability of $6.7 million in February, which approximates fair value. The Company expects to complete the previously announced workforce reduction in the second quarter of 2011, at which point the Company expects to substantially pay the remainder of the obligation.

	Workforce Reduction
Restructuring Balance, February 11, 2011	$ 6,659
Cash payments	(2,799)
Restructuring Balance, March 31, 2011	$ 3,860

The $6.7 million of costs associated with the restructuring are included in Research and development and General and administrative operating expenses in the condensed consolidated statements of operations as $5.0 million and $1.7 million, respectively, for the three months ended March 31, 2011.

8. State research and development credit exchange receivable

The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development income tax credits. The program provides for an exchange of research and development income tax credits for cash equal to 65% of the value of corporation tax credit available for exchange. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. At March 31, 2011 and December 31, 2010, the estimated amounts receivable under the program were $1.4 million and $1.3 million, respectively.

9. Property and equipment net

Property and equipment net consist of the following (dollar amounts in thousands):

	Estimated Useful Life (Years)	March 31, 2011	December 31, 2010
Land		$ 5,273	$ 5,273
Buildings	39-40	54,948	54,948
Building improvements	5-40	113,489	113,489
Machinery and equipment	3-15	73,878	73,812
Furniture, fixtures and office equipment	5-10	5,369	5,369
Computer equipment and software	3	16,332	16,306
Leasehold improvements		53	53
Construction in progress		19,026	14,496
		288,368	283,746
Less accumulated depreciation and amortization		(85,189)	(81,390)

Property and equipment net	$ 203,179	$ 202,356

Leasehold improvements are amortized over the shorter of the term of the lease or the service lives of the improvements. Depreciation and amortization expense related to property and equipment for the three months ended March 31, 2011 and 2010, and the cumulative period from February 14, 1991 (date of inception) to March 31, 2011 was $3.8 million, $4.2 million and $98.0 million, respectively. Capitalized interest recorded during the three months ended March 31, 2011 and 2010 was $0.4 million and zero, respectively.

10. Common and preferred stock

The Company is authorized to issue 200,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series designated by the Company s board of

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directors. No other class of capital stock is authorized. As of March 31, 2011 and December 31, 2010, 130,674,783 and 127,793,178 shares of common stock, respectively, were issued and outstanding. Included in the common stock outstanding as of March 31, 2011 are 9,000,000 shares of common stock loaned to Bank of America under a share lending agreement in connection with the offering of the $100 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015 (see Note 13 Senior convertible notes). Bank of America is obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to the Company on or about the 45th business day following the date as of which the entire principal amount of the notes ceases to be outstanding, subject to extension or acceleration in certain circumstances or early termination at Bank of America s option. The Company did not receive any proceeds from the sale of the borrowed shares by Bank of America, but the Company did receive a nominal lending fee of $0.01 per share from Bank of America for the use of borrowed shares.

In August 2010, the Company entered into an agreement with Seaside 88, LP (Seaside) for the sale of up to 18,200,000 shares